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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
12/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,949	SILLEKENS ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2, 4, 6, 8, 11-13, 15--22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4, 6, 8, 11-13, 15--22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/04/10 has been entered.

The response filed 11/04/10 to the Office action has been entered. Claims 2, 4, 6, 8, 11-13 and 15-22 are pending.

2. Applicant's arguments with respect to claims 2, 4, 6, 8, 11-13 and 15-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2, 4, 11-13, 16-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laue et al. (7374883, issued May 20, 2008) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)).

Laue et al. disclose a method for detecting Severe Acute Respiratory Syndrome-associated virus (SARS). A real time RT-PCR reaction is performed in which a forward primer binds to a region defined by nucleotides 69-98 of SEQ ID NO: 1 and a reverse primer binds to a region defined by nucleotides 123-168 of SEQ ID NO: 1 and a probe labeled with a fluorescent dye binds to a region defined by nucleotides 89-132 of SEQ ID NO: 1 for the detection (see column 2, lines 4-24). As indicated in the search report, the nucleotides 80 to 297 of SEQ ID NO: 1 comprise instant SEQ ID NOs: 3, 4, 7 (see the attached nucleic acid search report). SEQ ID NO: 4 of Laue et al. is 24 nucleotides in length and comprises the instant SEQ ID NO: 8 which is 21 nucleotides in length (see the attached nucleic acid sequence search report). SEQ ID NO: 4 of Laue et al. is used a probe for the detection (see column 6, lines 50-55). A PCR-derived construct comprises a promoter sequence for T7 RNA polymerase (see column 8, lines 2-7). The primers used in the method are 18-31 nucleotides in length (see column 2, lines 10-14).

Lowe et al. disclose a computer program for selecting oligonucleotide primers for PCR from a known sequence (pg. 1758, column 1) and the primer is specific and effective (see pg. 1757, the Abstract).

One of ordinary skill in the art would have been motivated to construct a pair of oligonucleotides within instant SEQ ID NOs: 3-4 and 7-8 for amplifying a target sequence of the

genome of SARS Coronavirus with a reasonable expectation of success because Laue et al. disclose a method of detecting SARS with a pair of primers and a known sequence, and Lowe et al. disclose a computer program for selecting oligonucleotide primers for PCR from a known sequence (pg. 1758, column 1) and the primer is specific and effective (see pg. 1757, the Abstract). It would have been prima facie obvious to construct a pair of oligonucleotides within the instant SEQ ID NOs: 3-4 and 7-8 for amplifying a target sequence of the genome of SARS Coronavirus as claimed.

5. Claims 2,8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briese et al. (20040265796, issued Dec. 30, 2004) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)).

Briese et al. disclose a PCR and real time PCR assay for detecting the SARS-associated coronavirus. The assay allows for rapid molecular detection and has improved sensitivity and specificity (see [0008]). A kit for the detection is also provided. The kit comprises a primer set comprising at least two nucleic acid sequences (see [0014]). As indicated in the search report, SEQ ID NO: 1 comprises instant SEQ ID NOs: 25 and 29 which are recited in claims 2 and 8 (see pg. 10 and the search report). SEQ ID NO: 1 includes the 3' non-coding region of the SARS-associated coronavirus genome and a portion of the N gene of the SARS-associated coronavirus genome (see pg. 2, [0019]).

The teachings of Lowe et al. are set forth in section 4 above.

One of ordinary skill in the art would have been motivated to construct a pair of oligonucleotides within instant SEQ ID NOs: 25 and 29 for amplifying a target sequence located within the gene encoding the nucleocapsid protein of the genome of SARS Coronavirus with a

reasonable expectation of success because Briese et al. disclose an assay of detecting SARS with a pair of primers from a known sequence, the assay allows for rapid molecular detection and has improved sensitivity and specificity (see [0008]) and Lowe et al. disclose a computer program for selecting oligonucleotide primers for PCR from a known sequence (pg. 1758, column 1) and the primer is specific and effective (see pg. 1757, the Abstract). It would have been prima facie obvious to construct a pair of oligonucleotides within SEQ ID NO: 25 and 29 for amplifying a target sequence located within the gene encoding the nucleocapsid protein of the genome of SARS Coronavirus as claimed.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laue et al. (7374883, issued May 20, 2008) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)) as applied to claims 2, 4, 11-13, 16-18 and 22 above, and further in view of Tyagi et al. (Nature Biotechnology, 1996 Vol. 14, pg. 303-308).

The teachings of Laue et al. and Lowe et al. are set forth in section 4 above. Laue et al. and Lowe et al. do not disclose the limitations of claim 15.

Tyagi et al. disclose molecular beacon probes that recognize and report the presence of specific nucleic acids in homogeneous solutions (see pg. 303, the Abstract).

One of ordinary skill in the art would have been motivated to apply a molecular beacon probe for detection as taught by Tyagi et al. because the probe is sensitive and can be used in a sealed tube (see pg. 303, the Abstract). It would have been prima facie obvious to apply a molecular beacon probe for detection.

7. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laue et al. (7374883, issued may 20, 2008) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)) as applied to claims 2, 4, 11-13, 16-18 and 22 above, and further in view of Compton et al. (Nature, 1991, Vol. 350(7), pg. 912-992).

The teachings of Laue et al. and Lowe et al. are set forth in section 4 above. Laue et al. and Lowe et al. do not disclose the limitations of claims 19 and 21.

Compton discloses a standard NASBA reaction which comprises a first primer with a promoter sequence at 5' end for recognizing T7 RNA polymerase and reagents for the reaction (see pg. 91, column 1).

One of ordinary skill in the art would have been motivated to apply a NASBA reaction for detection SARS nucleic acid in a sample with a reasonable expectations of success because the NASBA process requires fewer cycles than PCR to produce a desired amplification (see pg. 91, column 3). In addition including reagents in a kit for a NASBA reaction would have been a routine practice for conveniently performing a reaction. It would have been prima facie obvious to carry out a NASBA reaction and to make a kit including a NASBA reagent for detecting SARS nucleic acid in a sample.

8. Regarding the arguments filed 11/04/10, the response points to the examples from the specification showing these primer pairs for amplifying SARS CoV RNA exhibited better performance than others. However, this argument and the examples in the specification are not commensurate in scope with the instant claims, which are much broader and encompass a large number of primer pairs. There is no evidence of record that all of the primer pairs encompassed

in the genus recited in the claims would be expected to exhibit the same advantageous properties as the specific primer pairs which were tested. Claims limited to the tested primer pairs would not be subjected to this rejection. It is noted that this does not apply to claim 15, which is drawn to a single probe and not to a primer pair.

Allowable Subject Matter

9. Claim 6 is free of prior art.

10. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claim 6, no prior art has been found teaching or suggesting a pair of primers for amplifying a target sequence located within the gene encoding the nucleocapsid protein of SARS coronavirus consisting essentially of a first oligonucleotide being 10-50 nucleotides in length and comprising at least 10 contiguous nucleotides of SEQ ID NO: 15 and the complementary nucleotide sequence of SEQ ID NO: 15; a second oligonucleotide being 10-50 nucleotides in length and comprising at least 10 contiguous nucleotides of SEQ ID NO: 19 and the complementary nucleotide sequence of SEQ ID NO: 19.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Joyce Tung/
Examiner, Art Unit 1637
December 14, 2010